Testimony of Jonathan Cohen*
Environment, Technology, and Standards Subcommittee
Committee on Science
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Good afternoon. I am Jonathan Cohen, founder and CEO of 20/20 GeneSystems, a small biotechnology company based in Rockville, Maryland focused on developing and bringing to market innovative diagnostics for biodefense, cancer, and autoimmune diseases. Before starting 20/20 in 2000 I worked as in-house counsel for two publicly traded biotechnology companies.

As a company with eight employees owned by about a dozen individuals and a few institutional investors, the SBIR program has played a vital role in 20/20's progress and success. We are deeply concerned, however, that if the SBIR size standards were changed to permit companies owned and controlled by large venture capital firms to qualify for this small pool of funding we could loose our ability to continue to bring innovative products to market. We therefore urge that the size standards for this program be left intact and that companies that are not small businesses (as traditionally defined) instead look outside this 2.5% set-aside for appropriate and needed government support.

Likely Consequences of the Proposed Change to SBIR Size Qualifications

Because the SBIR application process is so resource intensive, especially at the NIH, opening up the program to companies owned and controlled by deep-pocketed investment houses presents a genuine risk that a significant percentage of available funds will be siphoned away from the very companies for which the SBIR program was created to support. In other words, the 2.5% set aside for small companies (as they have been traditionally defined) could quickly become 1% or 0.5%. Hundreds of small biotech companies throughout the country could be stalled or put out of business by this change with the following consequences.

First, it would shift funding away from areas of research underway at many small companies that is critical for public health and national security but out of favor with Wall Street. This includes biodefense, vaccine development, diagnostics, platform technologies, research tools, orphan disease therapies, agricultural biotechnology, environmental biotech, etc. For example, just after the anthrax mailings here on Capitol Hill in 2001 our company developed a novel method of screening suspicious powders and brought it to market the following year. Today our *BioCheck*™ test kit is routinely used by more than 300 federal, state, and local first responder organizations nationwide. Had we been owned and controlled by one or more large VC firms it is highly unlikely that this popular and important product would have been permitted to be developed and

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commercialized due to the relatively small market it addresses and liability risk as would be perceived by our large corporate owners.

Second, it would decrease support for high-impact, high-risk innovative research which small, independently owned companies historically excel at in favor of lower risk product development favored by most VCs today. The following observation by John F. Wong, Ph.D. who writes a monthly "Wall Street Biobeat" column in *Genetic Engineering News* accurately describes the current state of biotech investment:

> The biotech industry seems to be at a crossroads as it enters the second half of its 50-year cycle. **With the focus now on developing products that are already in clinical development, the industry appears to be moving away from its core strength of research and innovation.**
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> Frustrated by not reaping the benefits of the genomic and proteomic revolution of the 1990s, **biotech investors now seem to be more risk adverse. Their investment strategy is to focus on investing in companies with products in late stages of clinical development, which they believe will receive FDA approval**. (Emphasis added)[†]

This phenomenon was reiterated last week by several leading venture capitalists attending the annual meeting of the Biotechnology Industry organization:

> 'In the late 1990s, investors were willing to back early-stage technology phases of biotechnology,' said Jim Barett, an analyst and general partner of New Enterprise Associates. 'Now the investment community is moving toward later-stage projects. That means that early-stage projects are having difficulty raising money in this environment of risk discounting.'[‡]

However, what's best for Wall Street is not always best for America. VC's play a critical role in support of important segments of the biotechnology industry but blockbuster drugs are not the only need of our healthcare system. Diagnostics and new platform technologies, for example, receive little interest from large VCs but are essential for both biodefense and the emerging field of "personalized medicine" where the optimum therapies are tailored to patients based on their genetic disease profile.[§] Small biotech companies supported by the SBIR program are making major advancements in these important areas of R&D.

Furthermore, as reported by *Business Week* in March, individual Angel investors are filling some of the funding gap in high-risk early stage biotech investing that has been vacated by VCs, pouring nearly $2 billion into biotech last year, up more than 60% from

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[†] Genetic Engineering News, March 1, 2005, page 60.

[‡] "Investors: Show us the Drugs" Business Gazette, June 24, 2005

[§] The new paradigm of individualized medicine—strongly being pushed by the FDA-- will likely create demand for drugs to "niche" diseases, as defined by molecular profiling, with significantly smaller markets than traditional "blockbuster" drugs. This will likely increase the role of smaller biotech companies which can focus on smaller markets than large companies.

2002 (Attachment). Having raised over $2 million from Angels I can report, however, that this is very time consuming process that relies on the SBIR program to keep our R&D advancing and to provide these non-professional investors with independent validation of our technology.

Third, it would likely discourage the VC community from deploying the staggering $50 billion in unspent funds sitting in their coffers[**] by relying on SBIR grants rather than making follow-on investments in their portfolio companies. The proposed eligibility changes would simply be giving more "snow to the Eskimos."

Finally, it would hurt regions of the country with a small life science investor base, such as Maryland, to the benefit of Boston and San Francisco that are home to many seasoned biotech VCs. At the Maryland Technology Development Center (MTDC) in Rockville, a county operated facility that houses one of the largest numbers of biotech start-ups in the mid-Atlantic region not a single biotech company has raised a first round of venture capital since we became tenants there in 2001 but most have been funded through the SBIR program. The biotech entrepreneurs at the MTDC overwhelmingly oppose BIO's efforts to change the SBIR size standards.[††] Yet many of these companies are quite productive, and, like 20/20 have managed to develop and launch innovative successful biotechnology products with the support of the SBIR program, as well as Angel and some smaller institutional investors.

Simply put, a company owned and controlled by one or more large VC firms is not a small business and should not be entitled access the miniscule percentage of funds set aside for small businesses. These companies typically lack the culture and attributes of small, individually owned companies including the ability to "turn on a dime," take substantial risks, and address smaller and less predicable markets, including those unpopular on Wall Street. To permit this change would essentially take the "S" out of SBIR.

Large Entities Should Look Beyond SBIR

Proponents of changing longstanding definitions of "small business" are "barking up the wrong tree" by pressing for changes to the SBIR size standards when they should instead be focusing their efforts on the other 97.5% of the federal R&D pie not set aside for small individually owned companies. While historically most NIH funding has gone to support academic basic research, this has been changing over the last few years. Today there is

[**] Dow Jones VentureOne, March 2005

[††] It should be pointed out that BIO does not represent or speak for the entire biotechnology industry and certainly not most small companies. At best it speaks only for its membership which is heavily weighted by very large companies that are either publicly traded or have completed several large rounds of institutional investment. I was a member of BIO a few years ago and took part in several of its committee meetings. I was stunned by the extent to which these forums were dominated by professional lobbyists employed by large pharmaceutical companies and how few small company entrepreneurs took part in these meetings. In my view BIO lacks standing to address issues impacting small, individually owned companies since that community is so underrepresented in its membership and leadership.

an expanding number of programs available to businesses of all sizes at the NIH and other agencies for high-risk, high-impact R&D or the development of products with small or unpredictable markets such orphan drugs or vaccines to bioterror agents. These programs collectively have substantially more funding available than the SBIR program. For example, as reported last week in *The Wall Street Journal*, the NIH is beginning to offer to pay for and carry out early clinical trials of high-risk experimental drugs for certain diseases for which improved therapies have been lacking for decades. (Attachment) Pharmaceutical giant Eli Lilly is among the companies reportedly taking part in this new program.

Congress should encourage this trend and consider new initiatives, open to companies of all size, that help bridge the growing "valley of death" between basic discoveries and delivery to patients of innovative drugs, devices, and diagnostics.[⌗⌗] At the same time, the integrity of programs like SBIR that safeguard the viability and productivity of our nation's small risk taking biotech entrepreneurs must be protected.

Thanks for considering my testimony today.

[⌗⌗] This could include a new Advanced Healthcare Technology Development Program, modeled after the NIST ATP program, focused on supporting innovative platform technologies that improve disease diagnosis and therapy selection, drug development, and clinical research. Funding for high-risk technology development is severely lacking from both the NIH and private investors despite the significant impact this can have on our nation's healthcare system. At least 10% of the NIH budget should be set aside for high-impact technology development in fields not supported by VCs or corporations.